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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,295	10/23/2003	Vickie L. Conley	279.199US3	7116
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SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH 1600 TCF TOWER 121 SOUTH EIGHT STREET MINNEAPOLIS, MN 55402				
			EXAMINER LAYNO, CARL HERNANDZ	
			ART UNIT 3766	PAPER NUMBER

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/692,295

Applicant(s)

CONLEY ET AL.

Examiner

Carl H. Layno 10/16/05

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 35, 44 and 68-74 is/are allowed.
- 6) ☒ Claim(s) 22, 24, 33, 34, 36-38, 41, 42, 45, 48, 49, 52, 53, 55-57, 59, 65, 67, 75, 76 and 78-80 is/are rejected.
- 7) ☒ Claim(s) 23, 25-32, 39, 40, 43, 46, 47, 50, 51, 54, 58, 60-64, 66 and 77 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/3/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Preliminary Amendment

1. Acknowledgment is made of applicant's preliminary amendment and two month extension of time, which were received by the Office on July 23, 2005.
2. Claims 1-21 are canceled. Claims 22-80 have been added and are active.

Priority

3. Acknowledgment is made of applicant's claim for priority as a Continuation of U.S. Patent Application No. 10/021,861, filed on December 17, 2001, now U.S. Patent No. 6,671,557, which is a Continuation of U.S. Application Serial No. 09/378,106, filed on August 20, 1999, now U.S. Patent No. 6,353,761.

Information Disclosure Statement

4. Acknowledgment is made of applicant's Information Disclosure Statement (PTO-1449), which was received by the Office on March 3, 2004.

Drawings

5. Applicant's formal drawings were received by the Office on October 23, 2003 and have been approved by the Examiner.

Specification

6. The disclosure is objected to because of the following informalities:

- p.1, first paragraph, lines 5-8, applicant's reference to parent application 10/021,861 should be updated to reflect the new status of this case as U.S Patent No. 6,671,551.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 79 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, lines 4-5 of claim 79 refer to a threshold test based on a "predetermined algorithm". The Examiner could find no support in the specification for this "predetermined algorithm".

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 80 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, there is no antecedent basis for the term "the threshold test" (line 4).

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

12. Claims 22, 24, 33, 34, 36-38, 41, 42, 48, 49, 52, 53, 55-57, 59, 65, 67, 75, 76, and 78 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wang (EP 0 310 216 A2).

The Wang (EP 0 310 216 A2) European Patent describes an apparatus Fig.1 for detecting cardiac thresholds using induced electrical stimulation pulses. The apparatus comprises an implantable portion comprising intracardiac sensing and stimulation electrodes **10,20,70** introduced via catheters into a patient's heart (p.3, lines 49-50; p.5, lines 9-10) and an external

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user input-output device **80** for displaying processed results (p.3, line 51). Input-output device **80** displays anomalous cardiac waveforms as well as amplitudes of the inducing pacing pulse(s) (p.12, lines 17-18). Though not explicitly indicated, it would be obvious if not inherent to assume that these amplitudes represent current values, since the induced pulses **S1** are shown with current values in the waveform displays of Figs.7B and 7C.

In regard to claims 24, 33, 37, 38, and 52 applicant's attention is directed to block **114** of Figs. 6 and 14, which teaches that waveforms can be printed out on a printer. This would presumably include a strip chart printer.

In regard to claims 33, 41, 48, 75, 76, and 78, the data processing module **50** (Fig.1) performs the function of applicant's "communications module" by passing user information from input-output device **80** to stimulation generation module **60**. The applicant's attention is also directed to Fig.8, which appears to show a display with annotations to P, R, T, So, and S1, sensed and paced cardiac events, respectively, as well as current amplitude information for induced pulse S1.

In regard to claim 59, the Wang patent includes circuitry that tests and calculates a number of cardiac thresholds. See Table 1 (p.8) and Table 2 (p.12).

In regard to claims 65 and 67, applicant's attention is directed to Figs.7B, 7C, and 8, which show various current values used in the induced stimulation pulses S1 as well as the use of multiple S1 pulses (Fig.8).

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13. Claims 22, 36, 45, and 55 are rejected under 35 U.S.C. 102(e) as being anticipated by Hsu et al (US. 6,091,990)

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

The Hsu et al ‘990 patent describes a cardiac rhythm management system (Fig.2) including an implantable device **20** having both a pacing circuit **68** and a defibrillation circuit **74**, and an external programmer unit **60**. The programmer unit **60** (also shown in Fig.3) has a graphical display **102** (Fig.6), having a split screen, whose lower window **156** shows ECG and therapy pulse tracings **162,164** along with alphanumeric indications of their energy levels (in joules). See Fig.6.

In regard to claim 45, programming head **106** (Fig.3) performs the function of applicant’s communication module for communicating with implantable device **20**. In addition to the alphanumeric energy indicator on window **156** (Fig.6), applicant’s attention is directed to upper window **150**, which also shows time information on when arrhythmias and associated therapy pulses were delivered to the patient.

Allowable Subject Matter

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14. Claims 79 and 80 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

15. Claims 23, 25-32, 39, 40, 43, 46, 47, 50, 51, 54, 58, 60-64, 66, and 77 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

16. Claims 35, 44, and 68-74 are allowed.

17. The following is a statement of reasons for the indication of allowable subject matter:

Independent claims 35 describes details of a cardiac rhythm management system including the combination of an external user interface, a communications module, and a storage medium “adapted to store markers of paced and sensed events and a separate alphanumeric indicator of pacing-level energy associated with each of the paced markers”, the indicator of pacing-level energy providing “at least one of a voltage, a current, a pulsewidth, and an energy”. None of the prior art references taught the use of a “storage medium” capable of performing these tasks in conjunction with applicant’s other claimed elements; consequently, the Examiner deems this claim to be allowable.

Independent claim 44 also describes the details of a cardiac rhythm management system whose external user interface includes, among other elements, a “therapy marker” associated with therapy delivered by the implantable device. This “therapy marker” is to be printed or displayed along with an energy indicator, and a time of the “same instance of therapy” delivered

by the implantable device. Again no teaching could be found for printing or displaying this combination of marker information. As a result, the Examiner also deems claim 44 to be allowable.

Independent claim 68 describes a cardiac rhythm management system including the combination of a “visual output indicator of energy” and a “visual therapy marker”, similar to claim 44, and allowable over the prior art for the same reasons mentioned *supra* for claim 44. As a result, the Examiner also deems depending claims 69-74 to be allowable.

Conclusion

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (571) 272-4949. The examiner can normally be reached on 9/4/5.

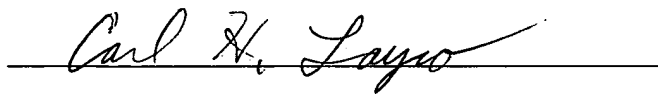
If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in cursive script, reading "Carl H. Layno", is written over a solid horizontal line.

CARL LAYNO
PRIMARY EXAMINER

CHL

10/14/2005